REMARKS

Status of the Claims

Claims 1-122 are pending in the application.

Claims 14-17, 21, 54-56 and 73-121 have been withdrawn pursuant to 37 C.F.R. §1.142.

Claims 1 and 8 have been amended by entry of this amendment.

Claim 17 has been reasserted and amended by entry of this amendment.

Claims 1-13, 17-20, 22-53, 57-72 and 122 remain under consideration with entry of this amendment.

Summary

Claims 1-13, 18-20, 22-53, 57-72 and 122 are pending in the application and were examined in the Office Action dated 9 April 2008. In the subject Office Action, the following claim rejections have been raised: **(a)** claims 1-13, 18-20, 22-24, 28-39 and 122 were rejected under 35 U.S.C. §112, second paragraph, on the basis of clarity; **(b)** claims 1-7, 10-12, 18-20, 22, 24, 29-35, 40-52, 57-65, 70 and 72 were rejected under 35 U.S.C. §102(b) as unpatentable over U.S. Patent No. 6,130,200 to Brodbeck et al. ("Brodbeck"); **(c)** claims 1-7, 10-13, 18-20, 22-39, 40-53, 57-72 and 122 were rejected under 35 U.S.C. §103(a) as unpatentable over International Publication No. WO 02/38185 to Dunn et al. ("Dunn") in view of U.S. Patent No. 6,432,415 to Osborne et al. ("Osborne"); and **(d)** claims 1-13, 18-20, 22-53, 57-72 and 122 were rejected under 35 U.S.C. §103(a) as unpatentable over Dunn in view of Osborne and in further view of U.S. Patent No. 5,614,206 to Randolph et al. ("Randolph"). Applicants respectfully traverse all pending claim rejections for the following reasons.

Overview of the Amendments

Applicants, by way of this Response, have re-entered claim 17 for consideration on the merits. In addition, applicants have amended claims 1, 8 and 17 in order to recite

the invention with greater particularity. More specifically, claim 1 has been amended to recite specific anesthetic agents that are included in the claimed compositions. Support for this amendment can be found throughout the specification and claims as originally filed, and in particular in claim 8 and in the specification at Paragraphs [0013], [0082], and [0089], and in the working examples. In addition, claim 1 has been amended to recite that the dosage form provides for a reduced initial bust after local administration. Support for this amendment can be found in the specification at Paragraphs [0086] and [0087]. Claim 8 has been amended to further limit the selection of anesthetics in light of the amendments to the base claim (claim 1). Claim 17 has been amended to more clearly recite that the "component solvent" is an additional element to the base (claim 1) composition. Support for this amendment can be found throughout the specification as originally filed, in particular at Paragraphs [0043], [0083] and [0084]. Accordingly, no new matter has been added by way of the amendments to claims 1, 8 and 17, and the entry thereof is respectfully requested.

The Election/Restriction under 35 U.S.C. §1.121

The Office has withdrawn claim 17 from consideration on the merits on the basis that the claim reads on a non-elected invention or species. Applicants traverse the withdrawal on the following basis.

Claim 17 as originally filed recites the composition of claim 1 comprising "a component solvent" selected from a group of recited solvents. Applicants refer the Office's attention to the specification, Paragraph [0043] at the top of page 8, line 4, wherein "component solvents" are defined as an optional addition to the base composition that contains the water-immiscible solvent. In addition, in Paragraphs [0083] and [0084], pages 16-17 of the specification, applicants further disclose the addition of such optional "component solvents" to the base formulation that includes the water-immiscible solvent that was the subject of the species election. Accordingly, the election of the water-immiscible solvent species (benzyl alcohol) has no preclusive effect with respect to the subject matter of claim 17, as that claim is still readable upon the elected species. Applicants therefore respectfully request that the Office re-enter claim

17 and examine that claim on the merits. Finally, applicants draw the Office's attention to the amendment made to claim 17 by way of this Response. As can be seen, the amendment clarifies that the "component solvent" is a further constituent of the bases composition of claim 1.

The Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1-13, 18-20, 22-24, 28-39 and 122 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. In particular, the Office has objected that applicants' recitation of a "low molecular weight" polymer in base claims 1 and 122 is indefinite, on the basis that "[a]bsent a definition in the specification, it is not clear what molecular weights are 'low' as claimed." Office Action at page 3. Applicants respectfully traverse the rejection.

In assessing a claim for compliance with 35 U.S.C. §112, second paragraph, one must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope, therefore providing the notice function of 35 U.S.C. §112, second paragraph. See *Solomon v. Kimberly-Clark Corp.*, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). In providing this notice function, a patent applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claims that make clear the boundaries of the subject matter for which protection is sought. In fact, a claim may not be rejected solely on the basis of the type of language used to define the subject matter for which patent protection is sought. *In re Swinehart*, 160 USPQ 226 (CCPA 1971). Further, the meaning of a claim term need only be apparent from the prior art or from the specification and drawings at the time an application is filed. In this regard, applicants need not confine themselves to the terminology used in the prior art; however, applicants are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention may be ascertained. See, e.g., *In re Morris*, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997) and *In re Prater*, 162 USPQ 541 (CCPA 1969).

In base claims 1 and 122, applicants have used the term "low molecular weight" to describe the selected polymer for use in the recited compositions. In the specification

as originally filed, applicants have provided a clear and precise definition for the term "low molecular weight polymer" that includes a specific overall weight average molecular weight range and a series of preferred sub-ranges, as well as the precise test that can be used to ascertain such molecular weight values. See Paragraph [0059], at page 11 of applicants' specification. The definition further provides precise chemical/physical feature of the selected low molecular weight polymer by requiring that that polymer is bioerodible. Applicants respectfully submit that their specification and claims therefore more than adequately apprise one of ordinary skill in the art the entire scope of the claimed invention, therefore satisfying the notice function of 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of the rejection of claims 1-13, 18-20, 22-24, 28-39 and 122 under 35 U.S.C. §112, second paragraph, is thus earnestly solicited.

The Rejection under 35 U.S.C. §102(b)

Claims 1-7, 10-12, 18-20, 22, 24, 29-35, 40-52, 57-65, 70 and 72 stand rejected under 35 U.S.C. §102(b) as anticipated by Brodbeck. Applicants respectfully traverse the rejection for the following reasons.

Applicants draw the Office's attention to the amendment to claim 1, wherein the anesthetic must be selected from the group consisting of: bupivacaine, levo-bupivacaine, ropivacaine, levo-ropivacaine, tetracaine, etidocaine, levo-etidocaine, dextro-etidocaine, levo-etidocaine, dextro-etidocaine, levo-mepivacaine, and combinations thereof. The Office has noted Brodbeck's disclosure of benzyl benzoate as the solvent (or use of benzyl benzoate in a combination of solvents) that can be used to form a gel vehicle that is then used to carry and release an additional component (an agent of interest that is intended for sustained release from the gel vehicle), and argues that benzyl benzoate is recognized as a topical anesthetic. Office Action at pages 4-5. Applicants respectfully traverse the rejection on the basis that due to the amendment to claim 1, all rejected claims now require selection from a list of specified long-acting anesthetics that excludes the benzyl benzoate solvent. Reconsideration and withdrawal of the rejection of claims

1-7, 10-12, 18-20, 22, 24, 29-35, 40-52, 57-65, 70 and 72 under 35 U.S.C. §102(b) is thus earnestly solicited.

The Rejections under 35 U.S.C. §103(a)

Claims 1-7, 10-13, 18-20, 22-39, 40-53, 57-72 and 122 stand rejected under 35 U.S.C. §103(a) as obvious over Dunn in view of Osborne. In particular, the Office asserts that the primary reference to Dunn describes a few of the components of applicants' recited compositions (a polymer and a solvent), but acknowledges that there are missing elements (a beneficial agent that is an anesthetic, and the specific particles sizes recited in claims 36-39). Office Action at pages 6-7. The Office attempts to overcome the missing disclosure from Dunn by looking to the secondary reference to Osborne which includes "local anesthetics" in a long laundry list of active agents. Office Action at page 8. The Office then asserts that selection of particle sizes "is routine optimization" and "clearly depends upon the needle through which the composition of Dunn needs to pass." Office Action at page 8. Applicants respectfully traverse the rejection.

The Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a). *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). According to the Federal Circuit, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

With regard to the Office's proposed combination as compared to applicants' original claims, the Office has failed to identify from its Dunn/Osborne combination dosage forms having a controllable efficacy ratio and/or efficacy ratios of 1-200 or 5-100 (see applicants' claims 2-4). With regard to applicants' recited particle sizes (for suspension formulations), applicants respectfully note that their specified particles sizes (250 μm, 5-250 μm, 20-125 μm and 38-63 μm) are unrelated to any concern about the ability to administer a formulation through a particular needle size since the recited

micron size ranges are orders of magnitude less than the smallest possible internal diameter of medical needles which very quickly approach millimeter sizes in lower gauge systems. Furthermore, with respect to the claims as now amended, the proposed Dunn/Osborne combination is also missing the following recited elements: **(a)** a long acting anesthetic selected from bupivacaine, levo-bupivacaine, ropivacaine, levo-ropivacaine, tetracaine, etidocaine, levo-etidocaine, dextro-etidocaine, levo-etidocaine, dextro-etidocaine, levo-mepivacaine, and combinations thereof; and **(b)** a reduced initial burst after local administration.

Applicants have disclosed and claimed new and useful anesthetic dosage forms that have an improved delivery performance (for example as evidenced with the tight control over delivery efficacy ratios), and at the same time enhanced safety profiles (the ability to reduce initial burst avoids potential harmful side effects from too much anesthetic being delivered in the first 24 hours of administration. The Office's proposed combination of Dunn and Osborne fails to establish that applicants' recited compositions were obvious. In addition, since the recited compositions were neither taught nor suggested by the Dunn/Osborne combination, it cannot be argued that the skilled person would have had a reasonable expectation of success in making those specific compositions. In other words, the Office's proposed combination of Dunn and Osborne fails to establish a *prima facie* case of obviousness of applicants' claimed compositions. Reconsideration and withdrawal of the rejection of claims 1-7, 10-13, 18-20, 22-39, 40-53, 57-72 and 122 under 35 U.S.C. §103(a) is thus earnestly solicited.

Claims 1-13, 18-20, 22-53, 57-72 and 122 stand rejected under 35 U.S.C. §103(a) as unpatentable over the combination of Dunn in view of Osborne and in further view of Randolph. The Office recites the same combination of Dunn and Osborne as discussed herein above, and then adds Randolph on the basis that it "teaches that bupivacaine is an anesthetic suitable for formulation in a sustained release formulation." Office Action at page 8. Applicants respectfully traverse the rejection for the following reasons.

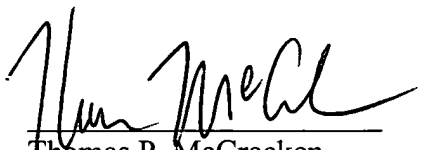
The failure of the Office's base combination (Dunn/Osborne) to render obvious applicants' recited compositions has been established above. In particular, applicants have disclosed and claimed new and useful anesthetic dosage formulations that have an

improved delivery performance (for example as evidenced with the tight control over delivery efficacy ratios), and at the same time has enhanced safety profiles (the ability to reduce initial burst avoids potential harmful side effects from too much anesthetic being delivered in the first 24 hours of administration). The addition of Randolph to this basic combination also fails to establish a *prima facie* case of obviousness of applicants' claimed compositions. This is because the specified performance requirements of applicants' recited compositions cannot be derived from Dunn/Osborne/Randolph when those references are considered alone or in any conceivable combination. Reconsideration and withdrawal of the rejection of claims 1-13, 18-20, 22-53, 57-72 and 122 under 35 U.S.C. §103(a) is thus earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

Respectfully submitted,



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